Magnesium Stearate	0.50%

REMARKS

Claims 26-48 are pending in the above-referenced application. As will be discussed in further detail below, claims 26 and 46 have been amended to more distinctly claim that which Applicants regard as their invention. No new matter has been added.

1. The Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 26 and 46 have been rejected under 35 U.S.C. 112, second paragraph. It is asserted that claim 26 is indefinite because the claim recites "and optionally a pharmaceutically acceptable carrier". Furthermore, it is asserted that claim 46 contains the trademark/trade name "Tabletosse 80".

In response, claim 26 has been amended to remove "optionally" and also now recites "one or more pharmaceutically acceptable carriers". Claim 46 has been amended so that "Tabletosse 80" has been replaced with the generic description, "lactose monohydrate".

In view of the claim amendments, the rejections under 35 U.S.C. 112, second paragraph have been overcome. Therefore, Applicants respectfully request that the rejections be withdrawn.

2. The Rejections Under 35 U.S.C. 103

Claims 26-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al., WO 99/19313 (hereinafter "Lohray"). It is asserted that Lohray teaches a process for the preparation of (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid compounds, their pharmaceutically acceptable salts and pharmaceutical compounds containing them. Furthermore, it is asserted that the instant claims differ from the reference of Lohray in that the instant claims have a limited scope. Therefore, it is concluded that since Lohray et al., teach the same compound (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid, composition and a similar process for the preparation of a composition comprising and the various forms of the compound (i.e. tablet, capsule, powder etc.) (claims 18-19) as instantly claimed, one of

ordinary skill in the art would have ample motivation to prepare such a composition comprising the same components for a similar intended purpose. The expected result would be a (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid composition in solid form for the effective treatment and/or prophylaxis of insulin resistance (type 2 diabetes) hypertension, hyperlipidemia, obesity and various other cardiovascular, renal and related disorders.

Applicants respectfully traverse the rejection. *Contra* to assertions made in the Office Action, there was absolutely no suggestion that regarding obtaining a composition of (-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier by mixing said (-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid or a pharmaceutically acceptable salt thereof with a carrier and compressing the mixture with excipients of less than 1% or a composition comprising said (-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable excipients with a water content below about 1% and an antioxidant. There was no disclosure or suggestion in Lohray regarding compression procedures in any of the methods disclosed. Furthermore, there was no suggestion in Lohray that it would be advantageous to obtain a composition having a low water content. Specifically, Lohray states on page 31, lines 14-20:

> The pharmaceutical composition may be in the forms normally employed, such as tablets, capsules, powders, syrups, solutions, suspensions and the like, may contain flavourants, sweeteners etc. in suitable solid or liquid carriers or diluents, or in suitable sterile media to form injectable solutions or suspensions. Such compositions typically contain from 1 to 20 %, preferably 1 to 10 % by weight of active compound, the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents.

Clearly, no direction is given as to what would be optimal. Actually, it would appear that the composition could be in either solid or liquid form. No indication is given that it would be advantageous to obtain a composition having a low water content.

At best this would be an "obvious to try" situation. An invention is merely "obvious to try" if the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful. *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 10 U.S.P.Q.2d 1843 (Fed. Cir. 1989). It is well known that the "obvious to try" standard is clearly erroneous. *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988).

In view of the above arguments, Applicants assert that the rejections under 35 U.S.C. 103 have been overcome. Therefore, Applicants respectfully request that the rejection be withdrawn.

4. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact Cheryl H. Agris by telephone at (914) 712-0093 if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: 4/14/03

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AMENDED CLAIMS-MARKED UP VERSION

26. (amended) A process for the preparation of a composition comprising (-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid or a pharmaceutically acceptable salt thereof, and ~~optionally a~~ at least one pharmaceutically acceptable carrier, comprising the step of forming a mixture of (-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid or a pharmaceutically acceptable salt thereof, and ~~one or more~~at least one pharmaceutically acceptable carriers and compressing the mixture with excipients of a water content below about 1%.

46. (amended)A composition comprising:

(-) 3-[4-[2-phenoxazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoic acid, arginine 0.18%

~~Tabletosse 80~~lactose monohydrate	96.12%
Avicel PH 102	3.00%
Cab-Osil M-3	0.20%
Magnesium Stearate	0.50%